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EXAMINER	
CHANG, VICTOR S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,539	AUDETT, JAY DOUGLAS	
	Examiner	Art Unit	
	Victor S. Chang	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-23,25-32 and 37-39* is/are pending in the application.

4a) Of the above claim(s) *37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18-23 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2007 has been entered. Applicants' amendments and remarks have been entered. Claims 14 and 31 have been amended. Claims 33-36 have been cancelled. New claims 37-39 have been entered. Claims 14-16, 18-23, 25-32 and 37-39 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. In response, the grounds of rejection have been updated as set forth below.

Election/Restrictions

4. Newly submitted method claims 37-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly added claims requires an additional backing layer, which carrying a primary or first drug, in addition to the backing layer carrying a secondary drug, therefore it changes the scope of the invention and is deemed to be a species of distinct embodiment over the embodiment of original presentation. There is no evidence that these embodiments are obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, new claims 33-36 are withdrawn from consideration as a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 14-16, 18-23, 25-32 are active. Finally, the examiner agrees with applicant's suggestion regarding the restriction of method claims at Remarks pages 8-9.

Claim Rejections - 35 USC § 112

5. Claims 14-16, 18-23, 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More particularly, amended independent claims 14 and 31 recites the term "adhesive". However, there is no proper antecedent basis for "adhesive", nor its cooperative structural relationship to the components of claimed invention being recited. Clarification is required.

Double Patenting

6. Claims 14-16, 18-23, 25-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 13, 21, 43, 54-57, 66, 90-92, 97-99 of copending Application No. 10/420,428 in view of Steinborn et al. [US 6080421] and FR 2249148 [Derwent abstract].

More particularly, the copending Appl. '428 discloses the structure and composition of the instant invention except that Appl. '428 is silent about that the outer layer is embossed, and

having a multilayer adhesive layer. However, FR '148 discloses that it is known that an adhesive tape of PET film having non-tacky hot melt EVA coating on both sides is used to join two surfaces and forms a bond by heat treatment. Steinborn's invention relates to a multilayer transdermal identified without printing inks, and discloses that embossing or printing are known methods to label transdermal therapeutic systems. It would have been obvious to label the invention of copending Appl. '428 with the embossing method of Steinborn, combined with FR '148 adhesive layer between the reservoir and embossable and breathable outer layer motivated by the desire to be able to identify the device.

This is a provisional obviousness-type double patenting rejection.

Rejections Based on Prior Art

7. Claims 14, 15, 18-23, 25, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421], and evidenced by Gale et al. [US 4904475].

Kydonieus' invention [abstract; col. 9, lines 4-5 and 38-42] relates to an article for administering pharmacologically active substances (drugs) transdermally. Fig. 4 shows an embodiment comprises a backing layer 34, a reservoir layer 35, and a diffusion membrane layer 36. The diffusion membrane layer 36 may be made of LLDPE (linear low density polyethylene). The backing is made of plastic, fabric (embossable, writable and breathable material), or aluminum foil.

For claims 14, 19 and 30, regarding the recited structural relationship between the layers (in terms the proximity to skin) merely defines the sequence of the layers as outer layer/tie

layer/base layer. Regarding the use language in the preamble, since it fails to contribute or limit the structure and/or composition of the device, it has not been given patentable weight. Regarding the term "secondary drug reservoir", since the specification [0032] discloses that the secondary drug reservoir may contain either a beneficial agent (primary or first drug) or an antagonist, the term "secondary drug reservoir" is interpreted as merely meaning any "pharmacologically active drug". In other words, the term "secondary" is interpreted as a use limitation, therefore lacks any patentable significance. This interpretation is commensurate with the fact that, depending on the medical treatments, the same drug can be used either as a "primary drug" or an "antagonist" (secondary drug). For example, while naltrexone is used as an "antagonist" in the instant invention (see claim 26), it is known that the same drug has been used as a drug for transdermal use, i.e., primary drugs, as evidenced by prior art reference Gale et al. [col. 3, line 6]. Kydonieus' backing layer, reservoir layer and diffusion membrane layer structurally correspond to the outer layer, tie layer and base layer of the claimed invention. Kydonieus is silent about having an embossed outer layer. However, Steinborn's invention relates to a transdermal drug delivery system and discloses that embossing is a known procedure for labeling (identifying) a transdermal drug delivery system [col. 2, lines 7-8]. It would have been obvious to one skilled in the art of transdermal drug delivery system to emboss the outer backing layer of Kydonieus' delivery system, as taught by Steinborn, motivated by the desire to provide identification. Regarding the newly added limitation that the secondary drug being "different" from the primary drug, since the term "secondary drug" is considered as a use language, the examiner holds that the Kydonieus' pharmacologically active substances read on the "secondary drug" as claimed. Regarding newly added limitation that the tie layer having a

polymer preventing adhesive enters the breathable material during embossing, since Kydonieus' delivery system does not require adhesive, Kydonieus reads on the invention as claimed. Further, applicant is reminded the term "adhesive" lacks antecedent basis, it is unclear what adhesive is being referred to. Finally, regarding the newly added use limitation that the instantly claimed backing construction is at the top of a transdermal drug delivery device, the examiner notes that since the claimed scope does not include the complete setup of a drug delivery system, the intended usage do not serve to distinguish structure over the prior art, it has not been given any patentable weight.

For claim 15, absence of any composition limitation for the component layers in the tie layer, they are indistinguishable and fail to preclude a single tie layer of Kydonieus from reading on all the claimed component layers.

For claims 18, 23, 25 and 28, Kydonieus teaches that the outer backing layer 34 may also be a semi-permeable membrane, which clearly encompasses a microporous backing material [col. 9, line 51]. Further, the Official notice that "polypropylene microporous membrane is a common backing material for a transdermal delivery system" is now taken as admitted prior art.

For claims 20 and 26, Kydonieus discloses that the reservoir layer is a pharmacologically active agent containing plastisol (polymer matrix). Kydonieus' pharmacologically active agent clearly encompasses the claimed pharmaceutically acceptable salts.

For claims 21 and 22, Kydonieus discloses that pharmacologically active agents are dispersed in high concentrations in a plastisol formed by fusing PVC particles and plasticizers at elevated temperature (thermoformed) [col. 3, lines 54-55 and col. 2, lines 47-51]. Further, the Official notice that "dispersing particulate pharmacologically active agents in a polymer matrix

for transdermal delivery system in not dissolved state is common and well known" is now taken as admitted prior art.

8. Claims 16, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421] and FR 2249148 [Derwent abstract].

The teachings of Kydonieus and Steinborn are again relied upon as set forth above.

For claims 16, 31 and 32, Kydonieus lacks a teaching of a multilayer tie layer between the backing layer 34 (outer layer) and the reservoir layer 35. However, FR '148 discloses that it is known that an adhesive tape of PET film having non-tacky hot melt EVA coating on both sides is used to join two surfaces and forms a bond by heat treatment. It would have been obvious to one of ordinary skill in the art to modify Kydonieus with an multilayered adhesive tape of FR '148 between the backing layer and the reservoir layer as well, motivated by the desire to provide an improved adhesion between the laminated layers. Regarding newly added limitation that no adhesive enters the breathable material during embossing, the examiner holds that since the combined teachings render the structure and composition of the adhesive layer and the backing obvious, a workable legible embossment without adhesive entering the breathable material is deemed to be an obvious routine optimization to one skilled in the art, dictated by the same utility which requires similar product properties.

9. Claims 27 and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421].

The teachings of Kydonieus and Steinborn are again relied upon as set forth above.

For claims 27 and 29, Kydonieus' backing layer 34, reservoir layer 35 and diffusion membrane layer 36 alternatively read on the base layer, tie layer and outer layer of instant invention, respectively. Since Kydonieus discloses that the backing layer 34 can be made of aluminum foil, it is inherently impermeable to drugs [col. 9, lines 4-5]. Again, regarding the use language in the claim, since it fails to contribute or limit the structure and/or composition of the device, it has not been given patentable weight. In particular, since the term "antagonist" merely a relative term opposite to "primary drug", and the same drug may be categorized differently in different conditions, therefore it fails to contribute structural limitation.

Response to Arguments

10. Pointing to a dictionary definition, applicant argues at Remarks page 9 that since neither US Appl. No. 10/420428 nor Steinborn et al. have a multilaminate tie layer, which must include at least two distinct layers together. However, since the dictionary definition states that "laminating" means "to make by uniting superposed layers of one or more materials", clearly the dictionary definition does not preclude one material in a single layer to read on all the layers in a multilaminate when the material (composition) is unspecified. The obviousness double patenting rejection is maintained. Further, since Appl. '428 discloses the structure and composition of the instant invention except that Appl. '428 is silent about that the outer layer is embossed, applicant's argument that neither reference talks about a backing that contains a drug is not taken.

Applicant argues at page 9 that Kydonieus devices are transdermal drug delivery systems, not backings. Applicant further argues that the combination of Kydonieus and Steinborn will

result in a drug delivery system to be used directly on skin, not a backing to be placed in a more complex drug delivery system. However, since statements of intended use do not serve to distinguish structure over the prior art, it has not been given any patentable weight.

Applicant's arguments at page 10 directed to copending 10/420428 individually is not taken, because applicant ignores that the basis of rejection is the combined teachings of prior art, and there is nothing whatsoever to prevent their teachings being combined, which render the claimed invention obvious.

Applicant argues at page 10 that the combined teachings of copending '428 and Steinborn would fail to prevent adhesive entering the porous backing during embossing. However, the combined teachings of copending 428, FR '148 and Steinborn render would have rendered the claimed invention obvious as set forth above.

Applicant argues at page 11 that

> "Regarding claims 14, 19, and 30, the Examiner asserted that the recited structural relationship between the layers are not given any patentable weight as outer layer/tie layer/base layer. Applicant submits that anyone skilled in the art clearly understands that the multilaminate backing construction of the present invention is composed of different layers of materials and is entirely different from the single layer backing of the prior art. The outer layer is a breathable material, the tile layer has a drug and ties the base layer to the outer layer and such that adhesive does not enter the breathable outer layer when embossed. Moreover, the tie layer is itself a ***multilaminate*** layer. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d, 180 USPQ 580 (CCPA 1974). Every element has to be considered. If the Examiner's logic were followed that different layers of different material are not given patentable weight, a rock will anticipate a house that has a roof on walls supported by a foundation."

However, since independent claims 14 and 31 lack structural and composition limitation, the term "multilaminate" does not distinguish it from the single layer of prior art, not prevents the single layer of prior art to read on all the layers of "multilaminate", such as the outer and inner

portions of the single layer would have read on the outer and inner layers of claimed "multilaminate" tie layer.

Applicant argues at page 11 that

> "the Examiner asserted that the primary drug and the secondary drug can be considered the same because the same drug can be considered a drug or an antagonist. Applicant respectfully disagrees. In the claims we specify the antagonist is the antagonist of the primary drug. Patents are written for those skilled in the art. Those skilled in the art will not consider an agonist drug to be an antagonist of itself. If the Examiner's view is to be taken literally, then to save a patient overdosed with a narcotic a physician would give more of the same narcotic (as an antagonist) to the patient. This practice would be a sure way to invite a malpractice suit. No person skilled in the art will follow this interpretation. However, to speed the prosecution of the application, Applicant has amended the claim to specify that the primary drug and the secondary drug are different."

However, as set forth above, since the claimed scope does not include the complete setup of a drug delivery system, the intended usage do not serve to distinguish structure over the prior art, it has not been given any patentable weight.

Applicant argues at page 13 that

> "Embossing a laminate with microporous membrane next to an adhesive causes problems, as clearly described in the present invention. Thus, if one were to replace the Steinborn backing (feature item reference 1 in Fig. 1 in Steinborn) with a microporous membrane and try to emboss by pressure, one would have exactly the problem described in paragraph 6 of the present application. Applicant submits Steinborn and Kydonieus cannot be combined in the way suggested by the Examiner."

However, since the combined teachings render the structure and composition of claimed invention obvious, it appears that applicant is arguing against its own invention.

Regarding the use limitations, Applicant argues at pages 14-15 that

> "This mode of delivery suggested by the Examiner would deliver an antagonist with the agonist, against all conventional practices by those skilled in the art. Thus, the Kydonieus drug reservoir should not render obvious what we have in the secondary drug reservoir.
> …
> Even if one would combine FR2249148 with Kydonius et al in view of Steinborn et al., the drug-containing adhesive would still be applied to the skin when the device is in use.

> Further, including hot melt adhesive as well as pressure sensitive adhesive in a tape increases the thickness of a tape, which is contrary to the conventional wisdom on desirable aesthetic characteristics."

However, again, since the claimed scope does not include the complete setup of a drug delivery system, since the intended use limitations do not serve to distinguish ***claimed*** structure over the prior art, it has not been given any patentable weight.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 7:00 am - 5:00 pm, Tuesday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor S Chang/
Primary Examiner, Art Unit 1794